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Dated: October 4, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–25973 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 184

[Docket No. 87G–0406]

Direct Food Substances Affirmed as Generally Recognized as Safe; Aminopeptidase Enzyme Preparation Derived From Lactococcus Lactis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of an aminopeptidase enzyme preparation derived from *Lactococcus lactis* (formerly known as *Streptococcus lactis*) in the manufacturing of cheddar cheese and in the preparation of protein hydrolysates is generally recognized as safe (GRAS). This action is in response to a petition filed by Imperial Biotechnology, Ltd.

DATES: Effective October 20, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a publication listed in new § 184.1985, effective October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in 21 CFR 170.35, Imperial Biotechnology, Ltd., Imperial College Rd., South Kensington, London, SW7 2BT, United Kingdom, submitted a petition (GRASP 8G0335) proposing that aminopeptidase from *L. lactis* be affirmed as GRAS as a direct human food ingredient.

FDA published a notice of filing of this petition in the Federal Register of February 23, 1988 (53 FR 5319), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). In its petition, Imperial Biotechnology, Ltd., relies on scientific procedures, primarily published scientific papers and books, corroborated by unpublished information, to demonstrate the safety of aminopeptidase enzyme preparation produced from *L. lactis* for use in the manufacturing of cheddar cheese and in the preparation of protein hydrolysates.

III. Identity, Technical Effect, and Production

A. Identity

Aminopeptidase enzyme preparation is a mixture of intracellular peptidases derived from the bacterium *L. lactis*. Peptidases are enzymes that cleave peptide bonds to liberate free amino acids or dipeptides (Ref. 1). The natural occurrence of peptidases in the cellular extracts of *L. lactis* and in extracts of cheese made with this organism is documented in the scientific literature (Ref. 2).

For simplicity, the trivial name aminopeptidase is used to describe the enzyme preparation. The Chemical Abstracts Service (CAS) Registry Number for aminopeptidase is 9031–94–1. The Enzyme Commission (EC) numbers of the enzymes present in aminopeptidase enzyme preparation are as follows: aminopeptidase, EC 3.4.11.1; tripeptide aminopeptidase, EC 3.4.11.4; dipeptidase, EC 3.4.13.11; proline dipeptidase, EC 3.4.13.9; dipeptidylpeptide hydrolases (EC 3.4.14.1–3) (Ref. 1). The agency finds that the petitioned preparation meets the requirements for enzyme preparations found in the Food Chemicals Codex, 3d ed. (1981), which is incorporated by reference in new § 184.1985.

B. Technical Effect

The progressive breakdown of milk proteins to peptides and amino acids during the ripening of cheese leads to the development of typical cheese texture and flavors. This process is catalyzed by aminopeptidase and other peptidases produced by the bacteria added to milk as starter cultures (Refs. 3 through 6). Also, these enzymes may be extracted from bacterial cultures and used in improving flavor and eliminating the bitterness of protein hydrolysates (Ref. 7), which are used in many foods for a variety of functions, including as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, protein sources, flavorings, and flavor enhancers. The petitioner intends to use the aminopeptidase enzyme preparation to accelerate flavor development during cheddar cheese ripening and to improve the flavor of protein hydrolysates used in various foods.

The petitioner has presented published information demonstrating that peptidase enzymes from *L. lactis* perform their intended technical effect in cheese manufacturing (Ref. 8). Furthermore, the petitioner provided a European patent office publication containing an approved patent application that demonstrates that the aminopeptidase enzyme preparation performs its intended technical effect in the manufacture of protein hydrolysates (Ref. 7). The petitioner also presented unpublished, corroborative studies demonstrating that the aminopeptidase enzyme preparation performs its intended technical effects in the manufacture of cheddar cheese and protein hydrolysates.

C. Production and Purification

The production process for aminopeptidase enzyme preparation, described in detail in GRASP 8G0335, may be summarized as follows: *L. lactis*, started from a pure culture, is aseptically grown at 30 °C in stainless steel fermenters in a medium containing lactose, casein hydrolysate, yeast extract, ascorbic acid, disodium hydrogen phosphate, magnesium sulfate, and polypropylene glycol P–2,000 as a defoaming agent. Samples of the medium are removed aseptically at various stages of fermentation and examined microscopically for typical morphology of the production organism and for the presence of contaminating organisms. During fermentation, the pH of the culture is maintained within a range of 6.4–6.6 with sodium hydroxide. Once the maximum cell density of the production organism, as measured by

optical density, has been reached, the fermentation is terminated by cooling the contents of the fermenter down to 5–10 °C. The bacterial cells are collected by centrifugation, resuspended in phosphate buffer, and the intracellular enzymes are released by physical disruption. The fraction containing aminopeptidase and other enzymes is separated from unwanted material by ultrafiltration or diafiltration. The enzyme fraction is dried, mixed, and packaged.

IV. Safety Evaluation

In evaluating the safety of aminopeptidase enzyme preparation as a food ingredient, the agency considered the following issues: (1) The safety of the producing organism; (2) the safety of the enzyme component; and (3) exposure levels of the enzyme preparation in food.

A. The Producing Organism

The producing organism *L. lactis* was formerly named *S. lactis*. However, genetic studies have demonstrated that this organism and several of its relatives are not as closely related to the other streptococci as was once thought, and the new information prompted their transfer to the newly created genus *Lactococcus* in 1985 (Ref. 9). Thus, in the older literature and various Federal regulations *L. lactis* is referred to as *S. lactis*.

L. lactis and its related organisms belong to a group of bacteria commonly known as the ''lactic acid bacteria'' (Ref. 10). All of the cheese standards FDA lists in part 133 (21 CFR part 133) provide for the use of lactic acid bacteria in the manufacture of cheese (for example, § 133.113 *Cheddar cheese*). Published information demonstrates that *L. lactis* and several of its subspecies are commonly used in cheese manufacturing (Refs. 2, 3, 4, 10, 11, and 12). The Catalogue of Strains of the National Collection of Food Bacteria in the United Kingdom lists several strains of *L. lactis* as cheese starter cultures (Ref. 13), and the Catalogue of Bacteria of the American Type Culture Collection cites various food uses for the same organism (Ref. 14).

Furthermore, certain strains of *S. lactis* are used to prepare two substances that FDA has affirmed as GRAS, nisin (21 CFR 184.1538) and starter distillate (21 CFR 184.1848). Additionally, the standards of identity for acidified sour cream (21 CFR 131.162); sour half-and-half (21 CFR 131.185); acidified sour half-and-half (21 CFR 131.187); and bread, rolls, and buns (21 CFR 136.110) provide for the use of lactic acid bacteria in the manufacture of these foods. *S. lactis* has been used to manufacture cheese, buttermilk, and other fermented foods for decades (Ref. 15). Lactic acid bacteria are the subject of a prior sanction by the United States Department of Agriculture (Ref. 16) and are listed as approved substances for use in several meat products in 9 CFR 318.7.

The information in the petition indicates that viable cells of the producing organism *L. lactis* may remain in the final product. The agency concludes that the presence of the viable cells of *L. lactis* in aminopeptidase enzyme preparation is not a safety concern, however, because: (1) The published information summarized above demonstrates the widespread food uses of this organism without any safety concerns; and (2) ''Bergey's Manual of Systematic Bacteriology,'' which describes the pathogenicity of *Streptococcus* species, contains no reference to pathogenicity of *S. lactis* (Ref. 17).

B. The Enzyme Component and Processing Aids

Published data demonstrate that aminopeptidase and other peptidases are naturally present in cheese prepared using *S. lactis* as a starter culture. In a study using a modified electrophoretic starch gel technique on cheddar cheese, researchers detected aminopeptidase activity in fractions of the cheese extracts (Ref. 2).

The petitioner also provided unpublished animal feeding studies as corroborative evidence of the safety of the aminopeptidase enzyme preparation. During a dietary range-finding study, rats were fed up to 2,000 milligrams (mg) aminopeptidase enzyme preparation per kilogram (kg) body weight (bw) per day (d) for 28 days. There were no reported deaths, clinical signs or group differences in liver and kidney weights that could be ascribed to treatment. Also, weight gains and food intake for all treatment groups were similar to those for controls.

During a second study, rats were fed aminopeptidase enzyme preparation for 13 weeks at doses up to 2,000 mg/kg bw/d. There were no deaths and no treatment-related clinical signs. Weight gains and food intake for all treatment groups were similar to those for controls. There were no macroscopic, pathologic, or histopathologic changes that could be ascribed to treatment with aminopeptidase enzyme preparation. Statistical analyses of organ weights showed no dose-related differences between treated and control groups.

The agency concludes from the evidence summarized above that the enzyme component of the aminopeptidase preparation does not raise safety concerns; therefore, the relevant safety issue becomes whether the enzyme preparations contain toxic contaminants. Enzyme preparations used in food processing are usually not chemically pure but contain, in addition to the enzyme component, materials that derive from the enzyme source, as well as from the manufacturing methods used to generate the finished enzyme preparation.

In accordance with § 170.30(h)(1), the enzyme preparations affirmed as GRAS in this document must comply with the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed., pp. 107–110. These include the requirement that aminopeptidase enzyme preparation from *L. lactis* be produced by methods and under culture conditions that ensure a controlled fermentation, thus preventing the introduction of bacterial cells that could be the source of toxic materials and other undesirable substances. Moreover, any compounds that become or are intended to become functional components of aminopeptidase enzyme preparation, such as water, salts, preservatives, or stabilizers, must be either GRAS ingredients or food additives approved as safe for this purpose. Therefore, the agency concludes that the presence of added substances and impurities derived from the enzyme source or introduced by manufacturing does not present a basis for concern about the safety of the enzyme preparation.

Additionally, the petitioner presented results of tests showing that aminopeptidase enzyme preparation derived from the strain of *L. lactis* used by the petitioner contains no detectable antibiotics that might promote the development of antibiotic resistance.

C. Estimated Exposure Levels

For exposure estimates, the agency has considered the proposed uses of aminopeptidase enzyme preparation in the manufacturing of cheddar cheese and in the preparation of protein hydrolysates. Estimates of enzyme use level and intake are usually based on the total organic solids (TOS) content of the enzyme preparation. The petitioner provided data indicating that the average TOS content of aminopeptidase enzyme preparation is 85 percent by weight. Based on information on consumption of cheese and processed foods containing protein hydrolysates and on the amount of aminopeptidase enzyme preparation needed to produce foods under conditions of current good

manufacturing practice (CGMP), the estimated daily intake (EDI) of aminopeptidase enzyme preparation, expressed as TOS, is 33 mg/person/d at the 90th percentile level of consumption of these products. As discussed above, aminopeptidase and other peptidases are naturally present in cheese made by using *S. lactis* as a starter culture (Ref. 2). The EDI at the 90th percentile level of consumption of aminopeptidase and other peptidases naturally present in cheese prepared with *L. lactis* as the starter culture expressed as TOS is 77 mg/person/d, which exceeds the EDI calculated above for added aminopeptidase enzyme preparation.

Moreover, the data obtained in the corroborative unpublished 13-week rat feeding study showed no adverse effects at the highest dose of 2,000 mg aminopeptidase enzyme preparation/kg bw/d. Correction of this value for TOS and application of a 1,000-fold safety factor produces, for a 60 kg person, an acceptable daily intake (ADI) of 102 mg TOS of aminopeptidase enzyme preparation/person/d, which exceeds the EDI reported above (33 mg TOS/person/d).

V. Conclusion

FDA has evaluated the published information in the petition, along with other corroborative information, and finds that the use of aminopeptidase enzyme preparation from *L. lactis* in the manufacturing of cheddar cheese and preparation of protein hydrolysates is GRAS.

Furthermore, these data show no potential risk from any foreseeable use of the aminopeptidase enzyme preparation. Therefore, in accordance with 21 CFR 184.1(b)(1), the agency is affirming that the use of aminopeptidase enzyme preparation from *L. lactis* is GRAS with no limits on its conditions of use other than CGMP.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Analysis of Impacts

FDA has examined the economic implications of this final rule affirming the GRAS status of the use of aminopeptidase enzyme preparation from *L. lactis* in the manufacturing of cheddar cheese and preparation of protein hydrolysates under Executive Order 12866 (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Since no increase in the health risks faced by consumers will result from this final rule, total costs are also zero. Potential benefits include the wider use of this substance to achieve its intended technical effects, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance. Affirming that the use of aminopeptidase enzyme preparation from *L. lactis* in the manufacturing of cheddar cheese and preparation of protein hydrolysates under conditions of CGMP is GRAS will expand product formulation possibilities for food manufacturers, including small entities. Therefore, under the Regulatory Flexibility Act, FDA has also determined that this rule will have a positive impact on small entities.

VIII. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act, 5 U.S.C. 553(d). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Enzyme Nomenclature 1978,'' pp. 300–309, Academic Press, NY, 1979.

2. Cliffe, A. J., and B. A. Law, ''An Electrophoretic Study of Peptidases in Starter Streptococci and in Cheddar Cheese,'' *Journal of Applied Bacteriology*, 47:65–73, 1979.

3. Perry, K. D., ''A Comparison of the Influence of *Streptococcus lactis* and *Str. cremoris* Starters on the Flavour of Cheddar Cheese,'' *Journal of Dairy Research*, 28:221–229, 1961.

4. Dawson, D. J., and J. T. Feagan, ''Bacteriology of Cheddar Cheese,'' *Journal of Dairy Research*, 24:210–224, 1957.

5. Law, B. A., M. E. Sharpe, and B. Reiter, ''The Release of Intracellular Dipeptidase from Starter Streptococci During Cheddar Cheese Ripening,'' *Journal of Dairy Research*, 41:137–146, 1974.

6. Reiter, B., Y. Sorokin, A. Pickering, and A. J. Hall, ''Hydrolysis of Fat and Protein in Small Cheeses Made Under Aseptic Conditions,'' *Journal of Dairy Research*, 36:65–76, 1969.

7. Parker, D. M., and D. Pawlett, ''Flavour Control of Protein Hydrolysates,'' European Patent Office Publication No. 0 223 560, Bulletin 87/22, May 5, 1987.

8. Law, B. A., and A. S. Wigmore, ''Accelerated Ripening of Cheddar Cheese with a Commercial Proteinase and Intracellular Enzymes from Starter Streptococci,'' *Journal of Dairy Research*, 50:519–525, 1983.

9. Schleifer, K. H., J. Kraus, C. Dvorak, R. Kilpper-Bälz, M. D. Collins, and W. Fischer, ''Transfer of *Streptococcus Lactis* and Related Streptococci to the Genus *Lactococcus* gen. nov.,'' *Systematic Applied Microbiology*, 6:183–195, 1985.

10. Jay, J. M., ''Modern Food Microbiology,'' 2d ed., pp. 255 and 265–266, D. Van Nostrand, NY, 1978.

11. Potter, N. N., ''Food Science,'' 4th ed., pp. 374–376, Van Nostrand Reinhold, NY, 1986.

12. Reiter, B., T. F. Fryer, A. Pickering, H. R. Chapman, R. C. Lawrence, and M. E. Sharpe, ''The Effect of the Microbial Flora on the Flavour and Free Fatty Acid Composition of Cheddar Cheese,'' *Journal of Dairy Research*, 34:257–272, 1967.

13. National Collection of Food Bacteria, Catalog of Strains, 3d ed., Reading, United Kingdom, pp. 116–126, 1986.

14. American Type Culture Collection, Catalogue of Bacteria and Phages, 8th ed., Rockville, MD, pp. 176–177, 1992.

15. Frazier, W. C., ''Food Microbiology,'' pp. 49 and 215, McGraw-Hill, NY, 1958.

16. Food Drug Cosmetic Law Journal, pp. 834–840, December, 1958.

17. ''Bergey's Manual of Systematic Bacteriology,'' vol. 2, edited by P. H. A. Sneath, pp. 1002 and 1065–1066, Williams and Wilkins, Baltimore, 1986.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drug and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 184.1985 is added to read as follows:

§ 184.1985 Aminopeptidase enzyme preparation derived from lactococcus lactis.

(a) Aminopeptidase enzyme preparation is derived from the nonpathogenic and nontoxicogenic bacterium *Lactococcus lactis* (previously named *Streptococcus lactis*). The preparation contains the enzyme aminopeptidase (CAS Reg. No. 9031–94–1; EC 3.4.11.1) and other peptidases that hydrolyze milk proteins. The preparation is produced by pure culture fermentation.

(b) The ingredient meets the specifications for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, as an optional ingredient for flavor development in the manufacture of cheddar cheese, in accordance with § 133.113 of this chapter, and in the preparation of protein hydrolysates.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

Dated: September 29, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–26054 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name from Miles, Inc., Agriculture Division, Animal Health Products to Bayer Corp., Agriculture Division, Animal Health.

EFFECTIVE DATE: October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Miles, Inc., Agriculture Division, Animal Health Products, P.O. Box 390, Shawnee Mission, KS 66201–0390, has informed FDA of a change of sponsor name to Bayer Corp., Agriculture Division, Animal Health. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Miles, Inc., Agriculture Division, Animal Health Products,'' and by alphabetically adding a new entry for ''Bayer Corp., Agriculture Division, Animal Health,'' and in the table in paragraph (c)(2) in the entry for ''000859'' by removing the sponsor name ''Miles, Inc., Agriculture Division, Animal Health Products'' and adding in its place ''Bayer Corp., Agriculture Division, Animal Health.''

Dated: October 5, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–25958 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Hoffmann-La Roche, Inc. One supplemental NADA provides for the addition of certain lasalocid-containing Type A medicated articles to dry, powdered milk replacer before reconstitution. The reconstituted Type C medicated feed is used to control coccidiosis in nonveal calves. Additionally, FDA is amending the regulations to reflect approval of another supplemental NADA which modifies the lasalocid feeding directions for control of coccidiosis in cattle.

EFFECTIVE DATE: October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, is the sponsor of NADA 96–298, which currently provides for the use of several concentrations of lasalocid sodium-containing Type A medicated articles in making Type C medicated cattle feeds (68 to 113 grams of activity per ton) for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*. The firm has filed a supplemental NADA that expands this use of the drug to nonveal calves using milk replacer powder.

Additionally, FDA concurred with another supplemental NADA which was filed to modify the feeding directions for lasalocid medicated feed when used to